K001995

SEP - 8 2000

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	QRS Diagnostic, LLC
2.	*Address:*	14755 27th Avenue No. Plymouth, MN 55447
3.	*Telephone:*	763-559-8560, Ext. 945
4.	*Contact Person:*	Jill R. Krall
5.	*Date Prepared:*	May 26, 2000
6.	*Registration Number:*	2133542

B. Device

1. *Proprietary*: SpirOxCard®, Diagnostic Spirometer and Pulse Oximeter
2. *Common/Generic*:
   a) Diagnostic Spirometer
   b) Pulse Oximeter
3. *Classification*:
   a) Diagnostic Spirometer
   b) Pulse Oximeter
4. *Class*: Class II
5. *Panel Code*:
   a) BZG
   b) DQA
6. *Regulation Number*:
   a) §868.1840
   b) §870.2700

K001995

C. Identification of Legally Marketed (Unmodified) Devices

Diagnostic Spirometry

1.	*Name:*	SpiroCard
2.	*Manufacturer:*	QRS Diagnostic, LLC
3.	*K Number:*	K973138
4.	*Date Cleared:*	October 28, 1998

Pulse Oximetry

1.	*Name:*	Model 8500
2.	*Manufacturer:*	Nonin Medical
3.	*K Number:*	K893221
4.	*Date Cleared:*	February 28, 1990

D. Description of the Device

The new product/modified device, the QRS Diagnostic, LLC SpirOxCard® Diagnostic Spirometer and Pulse Oximeter (SpirOxCard® PC Card), is the first fully functional Diagnostic Spirometer and Pulse Oximeter to be contained entirely within a PC Card.

The SpirOxCard® PC Card is sold with the PocketMedic® Software; a QRS Diagnostic custom data reporting software; a disposable, non-sterile, single patient use mouthpiece, for diagnostic spirometry testing. The Nonin Medical® Finger Clip Sensor is sold separately as an accessory for pulse oximetry testing. The user is required to load the QRS Diagnostic PocketMedic® Software on a user-supplied hand held personal computer, which uses Windows CE as the operating system.

Pulse oximetry facilitates patient care management by providing an approximation of arterial hemoglobin saturation with oxygen, and allows for the possibility of early detection of the catastrophic events associated with patient hypoxemia. Pulse oximetry is a state of the art, non-invasive method used to determine a patient's percent oxygen saturation (%SpO2) without having to obtain an arterial blood specimen. Also measured and reported during the pulse oximetry testing is the patient's pulse in beats per minute (bpm).

Spirometry is a primary pulmonary function test (PFT). The SpirOxCard® PC Card can be used for FVC, SVC, MVV and FEF testing. This test measures the air flow-rate and volume obtained during a patient's maximum forced exhalation/inhalation effort. It is the most commonly ordered PFT procedure and is practical to perform in any healthcare setting.

Combining the two diagnostic devices in to one device is very cost effective for the user. A Diagnostic Spirometer and a Pulse Oximeter are two devices that a Physician will use on a regular basis for patient care.

E. Intended Use Statement

Device Functionality: Diagnostic Spirometry and Pulse Oximetry
Spirometric Parameters: FVC, MVV, SVC and FEF
Oximetry Data Reported: %SpO2 and Pulse Rate
Patient Population: Male/Female, Pediatric to Adult
Environment of Use: Hospital, Clinic and Home Use

F. Required Components

- SpirOxCard PC Card (with Nonin® OEM2 Pulse Oximetry Module)
- Nonin Finger Clip Sensor
- PocketMedic® Software Disks (Includes Reporting Software and Driver Software)
- Plastic Disposable Mouthpiece
- Pressure Tubing
- User Manual
- Hand Held Personal Computer running Windows CE operating system (User Supplied)

G. Summary Table of Comparisons

The following summary tables of comparisons compare the modified device (SpirOxCard) to the predicate devices, SpiroCard and Nonin Medical Model 8500, for Diagnostic Spirometry and Pulse Oximetry respectively.

Diagnostic Spirometry

#	Area	New Device: SpirOxCard	Predicate Device: SpiroCard (Spirometry)	Same
1	Indications for Use	Diagnostic Spirometry FVC, SVC, MVV	Diagnostic Spirometry FVC, SVC, MVV	X
2	Fundamental Scientific Technology	differential pressure-to-flow conversion technique	differential pressure-to-flow conversion technique	X
3	Disposable Accessories	Mouthpieces (2)	Mouthpieces (2)	X
4	Sterile/Non-Sterile	Non-Sterile	Non-Sterile	X
5	Patient Contact Materials	Plastic Mouthpiece	Plastic Mouthpiece	X
6	Off-the-Shelf Software required for use	Windows CE	Windows CE	X
7	Software Driven	Yes	Yes	X

Pulse Oximetry

#	Area	New Device: SpirOxCard	Predicate Device: Nonin Model 850 (Pulse Oximetry)	Same
1	Indications for Use	Pulse Oximetry (Not for Continuous Use)	Pulse Oximetry (Not for Continuous Use)	X
2	Fundamental Scientific Technology	conventional dual wavelength pulse technique	conventional dual wavelength pulse technique	X
3	Accessories	Finger Clip Sensor	Finger Clip Sensor	X
4	Sterile/Non-Sterile	Non-Sterile	Non-Sterile	X
5	Patient Contact Materials	Plastic Finger Clip	Plastic Finger Clip	X
6	Software Driven	Yes	Yes	X

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2000

Ms. Jill R. Krall
QRS Diagostic, LLC
14755 27th Avenue N
Plymouth, MN 55447

Re: K001995
SpirOxCard®, Diagnostic Spirometer Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA, 73 BZQ
Dated: August 11, 2000
Received: August 16, 2000

Dear Ms. Krall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: *To be determined*

Device Name: SpirOxCard®, Diagnostic Spirometer and Pulse Oximeter

Indications for Use:

Intended Use:

Device Functionality: Diagnostic Spirometry and Pulse Oximetry
Spirometric Parameters: FVC, MVV, SVC and FEF
Oximetry Data Reported: %SpO2 and Pulse Rate

User Profile

Patient Population: Male/Female, Pediatric to Adult
Environment of Use: Hospital, Clinic and Home Use

Prescription Device by a Physician

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR OVER-THE-COUNTER USE

(optional Form 1-2-96)

Brian E. Harvey

Division of Cardiovascular & Respiratory Devices

510(k) Number K001995